

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D2043167	<b>(X3) Date Survey Completed</b> 04/14/2023
<b>Name of Provider or Supplier</b> Advanced Dermatology Pc	<b>Street Address, City, State</b> 449 North State Road Ste 203, Briarcliff Manor, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Mohs laboratory procedure manual, the temperature log sheets for 2022, the ambient temperature and humidity range requirements, 2022 Mohs accession log, and an interview with the office manager, the laboratory failed to monitor the room temperature and humidity for the testing area where Mohs patient sample processing occurs. FINDINGS: 1. The laboratory's procedure requires ambient temperature range between 68 - 78.6 F and humidity range between 0 - 60%. 2. The laboratory performed Mohs procedures on the following dates and failed to record the room temperature and humidity for the following: a. April 14, 2022, eight Mohs procedures were performed and patient results were reported. b. May 12, 2022, six Mohs procedures were performed and patient results were reported. c. July 7, 2022, seven Mohs procedures were performed and patient results were reported. 3. Office manager confirmed on April 14, 2023, at approximately 10:30 A.M. that the room temperature and humidity were not documented for the above dates.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other</p>

supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based upon the Toluidine Blue bottle label indications and confirmation in an interview with the office manager, the laboratory failed to ensure that stain utilized for Mohs slide processing did not exceed the indicated expiration dates. FINDINGS: The surveyor confirmed on April 14, 2023, at 11:00 A.M. through direct observation that expired Toluidine Blue stain was utilized for Mohs slide processing: 1. Toluidine Blue 0.1% lot # 113324 expired 2/27/2023. 2. Approximately ten patient samples were processed on March 16, 2023, utilizing the expired Toluidine Blue stain and patient results were subsequently reported.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the Competency Evaluation policy, testing personnel file records, and confirmed in an interview with office manager, the laboratory director failed to follow the established competency evaluation procedure and perform the six-month competency evaluation due June 2021 for the Mohs technician hired January 21, 2021.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of the Competency Evaluation policy, testing personnel file records, and confirmed in an interview with office manager, the laboratory director failed to follow the established competency procedure and perform the Mohs technician annual competency evaluation due January 2022.